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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,672	01/10/2005	Peter William Dettmar	102792-378 (P11085)	9407
27389 7590 08/20/2008 NORRIS, MCLAUGHLIN & MARCUS 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022			EXAMINER FLOOD, MICHELE C	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 08/20/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,672	Applicant(s) DETTMAR ET AL.	
	Examiner Michele Flood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on February 4, 2008 with the cancellation of Claim 15. With regard to the Notice of Non-Compliant Amendment, the examiner vacates this paper as it was inadvertently issued in error because printing of the filed paper did not make it readily visible that an actual amendment was made. The Examiner apologizes for any inconvenience experienced by Applicant.

Election/Restrictions

Applicant's election with traverse of Applicant's election of the species polyoxyethylene-based surfactants as it reads on Claim 6; the absence of polyvinyl pyrrolidone as it reads on Claims 16 and 20; the absence of isopropyl alcohol as it reads on Claim 17; the absence of a granulating agent as it reads on Claim 18; and the absence of solvents as it reads on Claim 16 in the reply filed on May 22, 2007 is acknowledged. Applicant's election with traversal has been fully considered and found to be persuasive.

Claims 1-14 and 16-20 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 16-20 are rejected under 35 U.S.C. § 112, first paragraph, for failing to provide prior support or antecedent basis for the language “(*Plantago psyllium*)” in Claim 1. Newly applied as necessitated by amendment.

The claims as set forth in the amendment filed on now recite an ingestible composition comprising ispaghula “(*Plantago psyllium*)”, colloidal silica, and an ingestible surfactant wherein said composition is in a form so that in use it is dispersed in a liquid prior to ingestion. However, the specification as originally filed provides only for compositions comprising ‘ispaghula’ obtained from *Plantago ovata*, as disclosed by Applicant on page 11, line 4 of the present specification.

Insertion of the above mentioned claim limitation has no support in the as-filed specification. The insertion of the limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genera which would show possession of the concepts for a composition comprising ispaghula obtained from (*Plantago psyllium*), with regard to Claim 1. There is only one exemplified ‘ispaghula’ obtained from *Plantago ovata*. This is not sufficient support for the new aforementioned genus. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitation is considered to be the insertion of new matter for the above reasons.

As the above-mentioned claim limitation could not be found in the present specification, the recitation of the claim limitations is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the polyethylene glycol" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 recites that the surface area of the claim-designated colloidal silica is between '50 and 400gm⁻². However, the surface area of granules is generally expressed as m²/gm. It would appear that the recitation of the aforementioned limitation is a typographical area. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 9-11, 13, 14 and 16-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Palkhiwala (A*), made evident by Denick, Jr. (D*) and/or Furst et al. (B*).

Palkhiwala teaches an ingestible composition comprising psyllium or ispaghula (Please note that ispaghula, psyllium and *Plantago ovata* are interchangeable terms used in the art referring to powdered psyllium seed husk or powdered psyllium. See Denick, Jr. and/or Furst.), colloidal silica, and an ingestible surfactant, namely Polysorbate 80 (TWEEN™) in granular or particular form, and a method of making

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thereof, wherein the amounts of the claim-designated ingredients (colloidal silica and surfactant) are one and the same as recited in Claims 5 and 13. See Column 7, line 10 bridging Column 7, line 25, wherein Palkhiwala teaches combining Polysorbate-80 with psyllium in the absence of a solvent, granulating agent or polyvinyl pyrrolidone.

Palkhiwala teaches that the process provides for the making of a powder that disperses readily in water without clumping. The amount of surfactant used in the process is in the range of from about 0.05 to 1.5 percent by weight, based on the total weight of the composition, and are selected from sorbitan esters and polyoxyethylene derivatives of sorbitan fatty acid esters, such as polyethylene 20 sorbitan monooleate or Polysorbate-80.

With regard to the claim limitation of each of Claim 3 and Claim 4, AEROSIL™ is the colloidal silica comprising the Palkhiwala' composition; therefore, a colloidal silica having a particle size of between 5nm and 5µm and a specific surface area between 50 and 400gm² is inherent to the prior art composition, as readily admitted by Applicant on page 6 of the specification, in its entirety.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 11, 12, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furst et al. (B*) in view of Palkhiwala (A*).

Furst teaches combining psyllium husk powder (ispaghula) obtained from *Plantago ovata* with a coating agent comprising a blend of hydroxypropylmethylcellulose and polyethylene glycol wherein the coating comprises 0.10 to 2% of the product in the making of an ingestible powder prepared without employment of any granulating agent. The composition taught by Furst readily disperses when placed on water.

The teachings of Furst are set forth above. Furst teaches the instantly claimed invention except for colloidal silica. However, it would have been obvious to one of ordinary skill in the art to combine the claim-designated ingredient to the teachings of Furst to provide the instantly claimed invention because Palkhiwala taught AEROSIL™ as a conventional excipient used in processes for formulating a powder bulk laxative composition involving mixing psyllium powder with a surfactant to provide a uniform coating thereto, as taught by Furst. Given the combined teachings as a whole, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add colloidal silica to the Furst' teachings to arrive at the claimed invention because at the time the invention was made Palkhiwala taught that adding AEROSIL™ to a surfactant coated psyllium powder provided for the making of an ingestible powder that disperses readily in water without clumping. Furthermore, it is well known in the art of pharmaceutical production that glidants, such as the colloidal silica taught by Palkhiwala, enhance the flow of a granular mixture by reducing interparticle friction.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claim-designated ingredient in the making of the claimed composition and claimed method of making thereof because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition and the claimed manufacture thereof are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-8, 11, 12 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halow (C*) in view of Palkhiwala (A*).

Halow teaches combining polyethylene glycol (molecular weight of between 200 and 40,000) with psyllium husk seed powder (also known in the art as ispaghula

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obtained from *Plantago ovata*) to provide a particular or granular ingestible composition prepared without employment of any solvent, isopropyl alcohol, granulating agent or polyvinyl pyrrolidone. The composition taught by Halow is liquid-dispersible.

The teachings of Halow are set forth above. Furst teaches the instantly claimed invention except for colloidal silica. However, it would have been obvious to one of ordinary skill in the art to combine the claim-designated ingredient to the teachings of Halow to provide the instantly claimed invention because Palkhiwala taught AEROSIL™ as a conventional excipient used in processes for formulating a powder bulk laxative composition involving mixing psyllium powder with a surfactant to provide a uniform coating thereto, as taught by Halow. Given the combined teachings as a whole, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add colloidal silica to the Halow' teachings to arrive at the claimed invention because at the time the invention was made Palkhiwala taught that adding AEROSIL™ to a surfactant coated psyllium powder provided for the making of an ingestible powder that disperses readily in water without clumping. Furthermore, it is well known in the art of pharmaceutical production that glidants, such as the colloidal silica taught by Palkhiwala, enhance the flow of a granular mixture by reducing interparticle friction.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claim-designated ingredient in the making of the claimed composition and claimed method of making thereof because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught

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by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition and the claimed manufacture thereof are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
August 4, 2008

/Michele Flood/
Primary Examiner, Art Unit 1655